K091387

510(k) Summary As Required By 21 CFR 807.92

JAN 22 2010

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Date Prepared: May 08, 2009

Device Trade Name: BTI Dental implant 5.5-6.5

Common Name: IMPLANT, ENDOSSEOUS, ROOT-FORM

Substantial Equivalence: K022258 BTI Dental Implant System
K053355 BTI Interna Dental Implant System
K063779 OsseoSpeedTM 4.0S – 6mm

Device Description: The BTI Dental Implant 5.5-6.5 is a self tapping, threaded dental implant intended for restoring missing teeth in partially or fully edentulous patients to restore the chewing capacity of patients. It is made of titanium and offers a variety of sizes including diameters: 4.5, 5.0, 5.5, 6.0 and lengths: 5.5, 6.5

Intended Use: BTI Dental implants 5.5 – 6.5 mm are intended to be used to restore missing teeth in partially or fully edentulous patients and/or for the fixation of overdentures to restore or enhance the chewing capacity of patients. The device should be used in a two-stage surgical procedure.

These implants are not indicated for immediate loading.

These implants are not indicated to support removable resilient retained restorations or angled abutments.

Technological Aspects: A comparison of the device features, intended use and other information demonstrate that the BTI Dental implants 5.5 – 6.5mm substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

JAN 22 2010

Mr. Alfredo Gómez
Regulatory Affairs Specialist
B.T. I. Biotechnology Institute, S.L.
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01510 Miñano (Alava)
SPAIN

Re: K091387
Trade/Device Name: BTI Dental Implant 5.5 - 6.5
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 17, 2009
Received: January 11, 2010

Dear Mr. Gómez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091387

Device Name: BTI Dental Implant 5.5 – 6.5

Indications For Use:

BTI Dental implants 5.5 – 6.5 mm are intended to be used to restore missing teeth in partially or fully edentulous patients and/or for the fixation of overdentures to restore or enhance the chewing capacity of patients. The device should be used in a two-stage surgical procedure.

These implants are not indicated for immediate loading.

These implants are not indicated to support removable resilient retained restorations or angled abutments.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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